

REMARKS

Status of the Claims

Prior to this amendment claims 1-2, 7-15 and 20-23 were pending, of which claims 8-14 and 20-22 were withdrawn from consideration.

Claim 1 is amended herein to delete recitation of “prostate hyperplasia.” Claims 23 is cancelled herein. Claims 24-27 are newly added, and are directed toward methods of providing an antiandrogen to a patient determined to be subject to prostate hyperplasia.

Rejections

The Office Action dated February 24, 2010 rejected under 35 U.S.C. § 102 as allegedly anticipated by U.S. Patent No. 6,544,564 (“Farley”) or U.S. Patent Publication No. 2002/0115708 (“Safe”). In particular, it was alleged that “[a] subject predisposed to an androgen-dependent pathology could virtually be anyone” and “[b]ased on [Farley teaching DIM and formulas to treat an androgen-insensitive PC-3 cell line], the inherency is evident with regard to a treatment of cancer.” *OA dated February 24, 2010*, at pp. 3-4. It is also alleged that Safe “teach that the DIM series of compounds . . . can be used for treating multiple cancers [including] two additional androgen-responsive prostate cancer cell lines” and that “it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to consider the teachings of Safe et al. in obviousness over the claimed invention.” *Id.*, at p. 5, 7.¹

Applicants have asserted that the claims are not directed toward “virtually anyone” but only toward a human patient subject or predisposed to an androgen-dependent pathology selected from the group consisting of prostate hyperplasia, acne, androgenetic alopecia and hirsutism, and that none of these pathologies are disclosed by Safe and Farley. *See, e.g., Response dated July 21, 2010*. Applicants further provided evidence that prostate hyperplasia and prostate cancer are different pathologies. *See, e.g., Response dated July 21, 2010* (citing Guess (2001) *Epidemiologic Reviews* 23:154-58, at p. 155 last full paragraph (stating “On the basis of available biologic evidence, benign prostatic hyperplasia appears to be etiologically unrelated to

¹ It is unclear whether the rejection based on Farley is under 35 U.S.C. 102 or 35 U.S.C. 103. However, the arguments provided below are relevant to both scenarios since Farley does not teach OR suggest providing an antiandrogen to a host subject or predisposed to prostate hyperplasia, acne, androgenetic alopecia, or hirsutism.

prostatic adenocarcinomas.”)). However, the Examiner maintains that the disclosure of prostate cancer by Safe reads on the claim recitation of prostate hyperplasia. *See, Advisory Action dated July 21, 2010*, at p. 3. Accordingly, it is Applicants understanding that patentability of the claims rests on the determination of whether Safe’s disclosure of DIM compounds for treating prostate cancer reads on the claimed method of administering a DIM compound for treating prostate hyperplasia.

Accordingly, solely to place the application in better form for appeal, Applicants have deleted recitation of “prostate hyperplasia” in independent claim 1. Since this claim was not rejected on any other basis, Applicants respectfully assert that this amendment places claims 1-2, 7, and 15 in condition for allowance. To clarify the issue on appeal, Applicants have also added new claims 24-27, which recite only the pathology of prostate hyperplasia and are otherwise identical to claims 1, 2, 7 and 15, respectively. Applicants respectfully submit that this amendment should only require a cursory review because the claim amendments presented herein do not add any new features and/or do not significantly alter the scope of the claims. Consequently, the claim amendments should not require any further search by the Examiner.

CONCLUSION


This Amendment is necessary as it clarifies and/or narrows the issues for consideration by the Board and was not earlier presented because Applicant believed that the prior response(s) placed this application in condition for allowance, for at least the reasons set forth in those response(s). Accordingly, entry of the present Amendment, as an earnest attempt to advance prosecution and/or to reduce the number of issues, is requested under 37 C.F.R. §1.116.

In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned by telephone at (415) 356-3064 or by fax at (415) 356-3099.

No fees are believed due, however the Commissioner is hereby authorized to charge any fees associated with this communication, and/or credit any overpayment to Deposit Account No. 50-2387.

Respectfully submitted,
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